Can You predict What’s Around the Bend?
With Turbo-Tandem, you can be assured you have the most versatile tool for treating disease.
TURBO-TANDEM
DESIGNED TO TREAT MULTIPLE MORPHOLOGIES IN LARGER VESSELS

EXCIMER LASER: PREDICTABLE, PROVEN RESULTS

The Turbo-Tandem™ was designed to treat a full range of morphologies in the SFA from small, focal lesions to long, diffuse lesions. And with Excimer Laser technology providing safe and proven therapy in multiple morphologies in the peripheral and coronary vasculature for close to twenty years, physicians should feel confident that the most versatile atherectomy solution is being provided for their patients. With no blades spinning or burrs sanding, the cool Excimer Laser technology is able to treat at the molecular level for maximized safety and control.

TURBO-TANDEM™
LASER GUIDE CATHETER WITH LASER ATHERECTOMY CATHETER

Versatile Performance
- Whether a long diffuse lesion or a small focal lesion, Turbo-Tandem can treat with predictable, proven results
- Turbo-Tandem can be combined with a Turbo-Elite™ catheter to cross a chronic total occlusion before debulking the artery

Proven
- The most published atherectomy method with over 70 peer reviewed journals supporting the efficacy and safety of laser atherectomy technology treating at the molecular level in both above and below the knee lesions
- Freedom from TLR of 77% for all patients, 85% in the stented group (CELLO)¹
- No major adverse events in the pivotal study (CELLO) of laser atherectomy technology for the approval of the Turbo-Tandem system at six months¹,³

Procedural Efficiency and Cost Effectiveness²
- With only one pass needed per quadrant, and no need to empty a nosecone or cool down a spinning burr, Turbo-Tandem can save time during your case
- No special wires or exact mix of lubricant needed to use Turbo-Tandem
- Turbo-Tandem is guaranteed. Spectranetics will provide a free replacement Turbo-Tandem catheter system if a physician uses the catheter and it falls short of the physician’s expectations

² Based on 2005-2010 IMS data and 2011 reimbursement rates.
CLELLO DATA HIGHLIGHTS

Independent angiographic core lab showed a 35% reduction in stenosis. IVUS results validate debulking with 112% luminal area gain, 60% was due to vessel expansion from the effects of Excimer Laser technology. Only Excimer Laser technology is able to cause vessel modification from breaking down the molecular bonds binding all types of plaque together. Breaking down molecular bonds allows for the vessel to relax and expand creating a unique result of luminal gain.

TURBO-TANDEM CASE RESULTS

SFA Pre Turbo-Tandem
74-year-old claudicant with 90% Left SFA stenosis.

SFA Post Turbo-Tandem
Stand alone procedure. 2 passes made in 4 quadrants with 7F Turbo-Tandem. No pilot channel required. Total treatment time < 60 seconds.

SFA Pre Turbo-Tandem
70-year-old diabetic claudicant with 95% SFA stenosis.

SFA Post Turbo-Tandem
No pilot channel required. 4 passes (1 each quadrant) at 45/25 followed by PTA with a 5mm x 80mm balloon @ 2 ATM for 3 minutes.

3 Atherectomy or any other surgical procedure has inherent risks. For a completing listing, see the IFU.
## TURBO-TANDEM Specifications

<table>
<thead>
<tr>
<th>Reference Number</th>
<th>472-110</th>
<th>482-110</th>
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<tbody>
<tr>
<td>Working Length</td>
<td>43</td>
<td>12</td>
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<tr>
<td>Wire Compatibility</td>
<td>0.014”(0.35mm)</td>
<td>0.014”(0.35mm)</td>
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<td>Sheath Compatibility</td>
<td>7F (≥0.098” / 2.5mm)</td>
<td>8F (≥0.113” / 2.9mm)</td>
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<td>Max Crossing Profile (Extended)</td>
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<td>Min Crossing Profile (Retracted)</td>
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<tr>
<td>Laser Catheter</td>
<td>2.0mm OTW</td>
<td>2.0mm OTW</td>
</tr>
</tbody>
</table>

## Important Safety Information

**INDICATIONS:**
Indicated for atherectomy of infrainguinal arteries.

**CONTRAINDICATIONS:**
No known contraindications.

See complete IFU for more information before attempting use of Turbo-Tandem.

**CONTRAINDICATIONS:**
- Do not use without a guidewire, as vessel injury may result.
- Do not extend the laser catheter distal tip marker band beyond the orientation marker band of the Turbo-Tandem System. This may result in damage to the device tip.
- Only advance and manipulate the Turbo-Tandem System under fluoroscopic guidance to confirm the location and orientation of the tip.
- Do not attempt to advance or retract the Turbo-Tandem System against resistance until the reason for the resistance has been determined by fluoroscopy or other means. This may result in deformation or detachment of the distal tip or kinking of the Turbo-Tandem System.
- If the catheter advances beyond or behind the orientation marker while lasing and advancing the system, stop and reassess before continuing. Continuing to advance the system or bias due to inappropriate reprocessing. Reuse of this single use device could lead to serious patient injury or death and voids manufacturer warranties.

**ADVERSE EVENTS:**
- Atherectomy or any other surgical procedure has inherent risks. For a complete listing, see the IFU.

**PRECAUTIONS:**
- Read the CVX-300® Excimer Laser System Operator’s Manual thoroughly before operating the CVX-300 Excimer Laser System to ensure safe operation of the system.
- This catheter has been sterilized using Ethylene Oxide and is supplied STERILE. The device is designated and intended for SINGLE USE ONLY and can not be re-sterilized and/or reused.
- The sterility of the product is guaranteed only if the package is unopened and undamaged. Prior to use, visually inspect the sterile package to ensure that the seals have not been broken. Do not use the catheter if the integrity of the package has been compromised.
- Always store the devices in a cool, dry place. Protect the device from direct sunlight and high temperatures (greater than 60°C or 140°F). After use, all equipment should be disposed of properly in accordance with specific requirements relating to hospital waste, and potentially biohazardous materials.
- During the procedure, appropriate anticoagulant and vasodilator therapy should be provided to the patient per the institution’s interventional protocols.
- The proximal coupler of the laser catheter connects only to the CVX-300 Excimer Laser System and is not meant to have any patient contact.
- Ensure the laser catheter tip is dry. A wet laser catheter tip may prevent successful device calibration.
- Do not use the Turbo-Tandem System if any damage is observed.
- If the laser catheter tip does not retract off the ramp, after depressing both release arms, pull the proximal disk back to retract the laser catheter. If the laser catheter does not retract prior to placing in the patient, set the device aside for product complaint management and open another device. If the laser catheter does not retract while in the patient, carefully grasp the distal disk component and slowly pull the proximal disk component away from the distal disk component to detach the handle into two separate parts. Do not move any portion of the system distally as this may cause harm to the vessel. Manually pull the proximal disk component attached to the laser catheter proximal until the laser catheter distal tip is off the ramp and remove both catheters together thru the introducer sheath.
- Ensure contrast media has been flushed from the intended vessel and treatment site prior to activating the laser system.
- Confirm the laser catheter is in the retracted state when advancing or retracting the Turbo-Tandem System without lasing.
- Do not use the device if its “Use By” located on the package labeling has passed.
- The Turbo-Tandem System is not designed to be used in total or sub-total occlusions.